

- Group II: Claims 5 to 7, directed to methods for determining the phenotype of a cell;
- Group III: Claims 8 to 11, directed to kits for assessing a patient's risk of having or developing inflammatory bowel disease;
- Group IV: Claim 12, directed to a method of doing business for assessing a patient's risk of having or developing an inflammatory bowel disease;
- Group V: Claim 13, directed to a method for treating a patient;
- Group VI: Claims 14 and 15, directed to nucleic acid arrays containing a solid support and nucleic acid probes that selectively hybridize to at least 25 different genes that are differentially expressed in IBD;
- Group VII: Claim 16, directed to a drug screening assay;
- Group VIII: Claim 17, directed to a method for treating an animal having an inflammatory bowel disease, and
- Group IX: Claim 18, directed to a pharmaceutical preparation for treating an animal having an inflammatory disease.

The Office Action is requiring restriction to a single disclosed invention under 35 U.S.C. §121. Applicant traverses the Restriction Requirement for the reasons stated below.

Nevertheless, in order to be responsive to the Office Action, Applicant elects the claim of Group VI, claims 14 and 15, directed to directed to nucleic acid arrays containing a solid support and nucleic acid probes that selectively hybridize to at least 25 different genes that are differentially expressed in IBD. Applicant reserves the right to pursue prosecution of the non-elected claims in a later filed application claiming the benefit of priority of the above-identified Application.

Applicant traverses the Restriction Requirement with respect to the division of the claims of Groups I, II, IV, V, VII and VIII. The Office asserts that the claimed methods of these groups of inventions use different steps, require different reagents and produce different products or results and therefore represent patentability distinct subject matter. The invention of Groups VI and IX are alleged to differ in respect to their properties, use and synthetic methodology for making them and also are alleged to represent patentability distinct subject matter. The invention of Groups VIII and VII are asserted to be distinct from the inventions of Group IX allegedly because the process of making or obtaining the invention of Group VII can be used to obtain a different product. The invention of Groups VIII and IX also are alleged to be distinct

inventions for similar reasons. The kit of Group III is alleged to be capable of use in any of several different methods of the restricted inventions. The Office concludes, based on the above, that the inventions of Groups I-IX have acquired a separate status based on their different classifications and divergent subject matter and that each group would require a separate search.

Applicant respectfully traverses the restriction requirement because the Office has failed to meet its burden for establishing a *prima facie* case for patentably distinct inventions. In this regard, the Office appears to reiterate certain guidelines for restriction of an invention. However, other than broad conclusory language such as the inventions “are related as product and process of use,” the Office Action appears to lack a rational for why the restricted groups of inventions satisfy these guidelines. Absent a specific showing or rational why each group of inventions are distinct the conclusory statements in the Office Action fail to satisfy the Office’s burden.

Further, Applicant submits that, while the claims of Groups I - IX are patentably distinct, a thorough search of the elected claims of Group VI will include art relevant to the claims of Groups I-V and VII-IX because the at least 25 different IBD genes contained within the array of Group VI claims are those genes identified or utilized in the methods of Groups I, II, IV, V, VII and VIII and the kit of Group III as well as the pharmaceutical preparation of Group IX. In contrast to the assertion in the Office Action, because all claims include the identification of or use of IBD genes as described and claimed in the application, a search of all groups of claims would not result in an undue burden on the Examiner. Therefore, rejoinder is respectfully requested.

Additionally, for example, Applicant respectfully draws the Office’s attention to the fact that the invention of Group II depends from the invention of Group I because these claims include “other IBD genes identified according to the method of claim1.” Therefore, at least Groups I and II should be rejoined. Moreover, the Office concludes that the restricted groups are differently classified. However, the Office has conceded on page 3 of the Office Action that Groups I, II and VII have been accorded the same classification. Namely, class 435, subclass 6. Therefore, Applicant respectfully requests rejoinder of the claims of all Groups and examination together.

The Office also is requiring a species election for the inventions of Groups I-IX allegedly because these claims are directed to a plurality of disclosed patentably distinct species. For the invention of Group VI, election is required to five (5) different IBD gene probes present in the array and the sequences of the probes and also election of a single solid support.

Applicant also respectfully traverses the election of species requirement. The elected group of claims are directed to at least 25 different IBD genes. To require less genes to be examined than that claimed is improper. Applicant contends that no species election should be required and the claims should be examined based on any of the disclosed IBD genes. However, if a species election is maintained, the minimum number of species examined should be that required by the claims, which is 25 different IBD genes. Therefore, reconsideration and withdrawal is respectfully requested.

To comply with the election of species requirement, Applicant elects for initial prosecution the following five (5) IBD gene probes GR03, Genbank accession no. X53800; Neutrophil lipocalin (HNL), Genbank accession no. S75256; Regenerating islet-derived 1 (REG1B), Genbank accession no. L08010; Elafin, Genbank accession no. L10343, and Collagen 6A3, Genbank accession no. X52022. Further, Applicant elects a chip as the species of solid support for initial prosecution. A chip is one of several enumerated exemplary species of solid supports described, for example, at page 5, lines 31-33, and at page 28, lines 12-14.


For the reasons set forth above, Applicant requests reconsideration and remove the Restriction and Election of Species Requirements. Examination of all groups of claims would not pose a serious burden on the Examiner because they all encompass IBD genes and the species election is improper. If rejoinder is denied for all or some of the restricted claims, Applicant respectfully requests a “second-eye review” as now implemented under the Restriction Practice Action Plan. Under the Action Plan, rejoinder practice is viewed favorably when examination of claims together would not pose a serious burden on the Examiner.

Serial No.: 10/084,892

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

MCDERMOTT WILL & EMERY LLP



David A. Gay  
Registration No. 39,200

4370 La Jolla Village Drive, Suite 700  
San Diego, CA 92122  
858.535.9001 DAG:cec  
Facsimile: 858.597.1585  
**Date: August 12, 2004**